

General

Guideline Title

American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer.

Bibliographic Source(s)

Saslow D, Solomon D, Lawson HW, Killackey M, Kulasingam SL, Cain J, Garcia FA, Moriarty AT, Waxman AG, Wilbur DC, Wentzensen N, Downs LS Jr, Spitzer M, Moscicki AB, Franco EL, Stoler MH, Schiffman M, Castle PE, Myers ER, ACS-ASCCP-ASCP Cervical Cancer Guidelines Committee. American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology screening guidelines for the prevention and early detection of cervical cancer. *CA Cancer J Clin*. 2012 May;62(3):147-72. [158 references] [PubMed](#)

Guideline Status

This is the current release of this guideline.

This guideline updates a previous version: Saslow D, Runowicz CD, Solomon D, Moscicki AB, Smith RA, Eyre HJ, Cohen C. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. *CA Cancer J Clin* 2002 Nov-Dec;52(6):342-62. [88 references]

Recommendations

Major Recommendations

Age to Begin Screening

Cervical cancer screening should begin at age 21 years. Women aged younger than 21 years should not be screened regardless of the age of sexual initiation or other risk factors.

Screening Periodicity

Women at any age should NOT be screened annually by any screening method; rather, recommended screening intervals for women are based on age and clinical history.

Women Aged 21 to 29 Years

For women aged 21 to 29 years, screening with cytology alone every 3 years is recommended. For women aged 21 to 29 years with 2 or more consecutive negative cytology results, there is insufficient evidence to support a longer screening interval (i.e., more than 3 years).

Human papillomavirus (HPV) testing should not be used to screen women in this age group, either as a stand-alone test or as a cotest with cytology.

Women Aged 30 to 65 Years

Women aged 30 to 65 years should be screened with cytology and HPV testing ("cotesting") every 5 years (preferred) or cytology alone every 3 years (acceptable). There is insufficient evidence to change screening intervals in this age group following a history of negative screens.

Management of Women With HPV-Positive, Cytology-Negative Cotests

Women cotesting HPV positive, cytology negative should be followed with either (as noted in the interim American Society for Colposcopy and Cervical Pathology [ASCCP] guidelines): Option 1) repeat cotesting in 12 months or Option 2) immediate HPV genotype-specific testing for HPV16 alone or for HPV16/18. If cotesting is repeated at 12 months, women testing positive on either test (HPV positive or low-grade squamous intraepithelial lesion [LSIL] or more severe cytology) should be referred to colposcopy; women testing negative on both tests (HPV-negative and atypical squamous cells of undetermined significance [ASC-US] or negative cytology) should return to routine screening. If immediate HPV genotype-specific testing is used, women testing positive for HPV16 or HPV16/18 should be referred directly to colposcopy; women testing negative for HPV16 or HPV16/18 should be cotested in 12 months, with management of results as described in option 1.

Women cotesting HPV positive, cytology negative should not be referred directly to colposcopy. Furthermore, they should not be tested for individual HPV genotypes other than HPV16 and HPV18. The use of HPV genotype-specific testing for HPV16 or HPV16/18 is recommended only for the management of HPV-positive, cytology-negative women. Currently, there is insufficient evidence to support the use of non-HPV biomarkers.

Management of Women With HPV-Negative, ASC-US Cytology Results

Women with ASC-US cytology and a negative HPV test result should continue with routine screening as per age-specific guidelines.

Screening With HPV Testing Alone

In most clinical settings, women aged 30 years to 65 years should not be screened with HPV testing alone as an alternative to cotesting at 5-year intervals or cytology alone at 3-year intervals.

Women Aged Older Than 65 Years

Women aged older than 65 years with evidence of adequate negative prior screening and no history of cervical intraepithelial neoplasm (CIN) 2+ within the last 20 years should not be screened for cervical cancer with any modality (adequate negative prior screening is defined as 3 consecutive negative cytology results or 2 consecutive negative cotests within the 10 years before ceasing screening, with the most recent test occurring within the past 5 years). Once screening is discontinued it should not resume for any reason, even if a woman reports having a new sexual partner.

Women Aged Older Than 65 Years With a History of CIN2, CIN3, or Adenocarcinoma In Situ

Following spontaneous regression or appropriate management of CIN2, CIN3, or adenocarcinoma in situ, routine screening should continue for at least 20 years (even if this extends screening past age 65 years).

Women Who Have Undergone Hysterectomy and Have No History of CIN2+

Women at any age following a hysterectomy with removal of the cervix who have no history of CIN2+ should not be screened for vaginal cancer using any modality. Evidence of adequate negative prior screening is not required. Once screening is discontinued, it should not resume for any reason, including a woman's report of having a new sexual partner.

Screening Following Vaccination: Looking to the Future

Recommended screening practices should not change on the basis of HPV vaccination status.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Cervical cancer
- Cervical intraepithelial neoplasia (CIN)

Guideline Category

Diagnosis

Prevention

Screening

Clinical Specialty

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Preventive Medicine

Intended Users

Advanced Practice Nurses

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To update the 2002 American Cancer Society guideline pertaining to early detection of cervical neoplasia and cancer
- To address age-appropriate screening strategies, including the use of cytology and high-risk human papillomavirus (HPV) testing, follow-up (e.g., the management of screen positives and screening intervals for screen negatives) of women after screening, the age at which to exit screening, future considerations regarding HPV testing alone as a primary screening approach, and screening strategies for women vaccinated against HPV16 and HPV18 infections

Target Population

Women aged 21 and over in the general population

Note: These guidelines do not address special, high-risk populations who may need more intensive or alternative screening. These special populations include women 1) with a history of cervical cancer; 2) who were exposed in utero to diethylstilbestrol (DES); and 3) who are immunocompromised (e.g., infection with the human immunodeficiency virus).

Interventions and Practices Considered

1. Cytology testing for cervical cancer
2. Cytology and human papillomavirus (HPV) testing ("cotesting")
3. HPV testing alone (discussed but not recommended in most clinical settings)
4. Genetic testing for HPV varieties 16 and 18

5. Optimal cytology screening intervals and cotesting screening intervals for cervical cancer
6. Screening strategies based on age
7. Management of discordant combinations of cytology and HPV results (e.g., HPV positive, cytology negative and HPV negative, atypical squamous cells of undetermined significance [ASC-US] results)
8. Exiting women from screening (based on age and hysterectomy status)

Major Outcomes Considered

- Cervical cancer deaths
- Cervical cancer cases
- Detection of cervical intraepithelial neoplasia grade 3 (CIN3)
- False positive results/unnecessary colposcopies
- Quality of life
- Treatment complications

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

An initial literature search for terms relevant to all the Working Groups was performed, and abstracts were reviewed by Data Group members. Articles meeting initial inclusion criteria were retrieved and distributed to each Working Group as appropriate. The search included articles from 1995 through July 5, 2011 (see Fig. 1 and Fig. 2 in supporting information [see the "Availability of Companion Documents" field]).

Number of Source Documents

Group 1: Optimal Screening Intervals for Cytology-based Screening: 18 articles

Group 2: Screening Strategies for Women 30 Years and Older: 201 articles

Group 3: Management of Women with Human Papillomavirus (HPV)-Positive, Cytology-Negative Results and Management of Women with HPV-Negative, Atypical Squamous Cells of Undetermined Significance (ASC-US) Results: 47 articles

Group 4: Exiting Women from Screening: 53 articles

Group 5: Looking to the Future – Impact of HPV Vaccination: 33 articles

Group 6: Looking to the Future - Potential Impact of Molecular Screening: 106 articles

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Grading of Recommendations Assessment, Development, and Evaluation

High: The committee is confident that the true effect lies close to what was found in the research.

Moderate: The true effect is likely to be close to what was found, but there is a possibility that it is substantially different.

Low: The true effect may be substantially different from what was found.

Very Low: The committee is very uncertain about the effect.

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Benefits and Harms

The 6 Working Groups independently considered a series of screening and management questions. (See the "Description of the Methods Used to Formulate the Recommendations" field for a list of the groups.) It was recognized that different groups of experts could evaluate the same data for related questions and reach different conclusions because of differences in weighing the benefits and harms of screening. Therefore, the main outcomes for benefits and harms were harmonized across Working Groups as defined in the original guideline document.

Evidence Review

Each Working Group took the initially defined areas and formulated specific questions using the Grading Recommendations Assessment, Development, and Evaluation (GRADE) framework. From an initial list of potential outcomes identified by the Data Group, each Working Group defined 3 to 4 outcomes as "critical," 3 to 4 outcomes as "important," and 3 to 4 outcomes as "useful" (see supporting information [see the "Availability of Companion Documents" field] for a list of outcomes). Members of the Working Groups then reviewed each article to determine whether data were available on critical or important outcomes. The guideline developer did not perform formal data synthesis or meta-analyses to create single summary estimates for each outcome/intervention pair. Instead, summary data from each included article, along with a quality grade of "high, moderate, low, or very low" were presented to the group, with a subsequent quality grade for the entire body of evidence for a given outcome/intervention pair.

The GRADE system does not specifically address modeling studies, which were frequently the only evidence available for comparing alternatives, particularly different screening intervals. Because modeling integrates evidence from a wide range of sources of varying quality, the Working Groups considered individual modeling studies as "low-" quality evidence, but, if the individual studies followed best practices for model-based analyses, and the results were consistent across studies done by different groups using different methods, the rating of the overall body of evidence based on modeling could be graded as being of "moderate" quality.

Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

Description of Methods Used to Formulate the Recommendations

Guideline Development and Organization

From 2009 to 2011, the American Cancer Society (ACS), the American Society for Colposcopy and Cervical Pathology (ASCCP), and the American Society for Clinical Pathology (ASCP) worked collaboratively to convene an expert panel to develop new screening recommendations based on a systematic review of the available evidence. The process was overseen by a Steering Committee comprised of representatives from the sponsoring organizations, other stakeholder organizations and agencies, and experts representing multiple disciplines (see "Acknowledgements" in the original guideline document for names of all committee members). An independent Evidence Evaluation Committee (the "Data Group") comprised of experts in literature reviews, evidence evaluation, and data analysis had primary responsibility for the overall development and implementation of the guidelines process, and for providing feedback and guidance to the Working Groups. Six topic areas to be addressed by the

recommendations were identified by the Steering Committee. A Working Group comprised of experts on a particular topic and representing different disciplines was assigned to each area, with each Working Group having a member of the Data Group serving as a liaison. Each group met regularly via teleconference, including Web-based conferences for all participants to review specific methodologic issues.

The 6 working groups addressed the following topic areas:

1. Optimal cytology screening intervals.
2. Screening strategies for women aged 30 years and older.
3. Management of discordant combinations of cytology and human papilloma virus (HPV) results (e.g., HPV positive, cytology negative and HPV negative, atypical squamous cells of undetermined significance [ASC-US] results).
4. Exiting women from screening.
5. Impact of HPV vaccination on future screening practices.
6. Potential utility of molecular screening (specifically, HPV testing for primary screening was assessed as a potential future strategy).

The working groups were instructed to propose evidence-based cervical cancer prevention strategies that best serve women, specifically balancing the benefits and harms of screening and, in some cases, management of screening results. They were specifically directed not to consider financial cost in making their recommendations.

Strength of Recommendation

Based on the initial grading of evidence, each Working Group formulated an initial summary recommendation, graded as "strong" or "weak," based on the overall quality of the evidence for outcomes considered "critical," as well as additional criteria such as variation in patient preferences (if data were available) and feasibility of obtaining additional evidence.

Members of the Steering Committee and Data Group, as well as the other Working Groups, reviewed these recommendations and corresponding rationale and provided feedback. After revision, the draft recommendations and rationale were posted on the ASCCP Web site for public comment from October 19, 2011 to November 9, 2011. The public comments were distributed to each Working Group, and revisions were made to address or clarify issues raised. However, each Working Group had the ultimate authority and responsibility for the (revised) draft recommendations presented at the symposium for consideration.

Consensus Conference

A symposium was held November 17 through 18, 2011 to discuss, revise as necessary, and vote on the final recommendations. In addition to the members of the Steering Committee, Data Group, and Working Groups, representatives from other stakeholder organizations were invited (see supporting information for list). Each Working Group presented its evaluation of the evidence and draft recommendations. After the presentation, there was an open discussion, followed by voting on the recommendations, including both the wording of the recommendation and the strength of the recommendation. A two-thirds majority was required for a recommendation to be accepted; if this threshold was not achieved, the recommendation was revised by the Working Group and brought back to the plenary participants for voting. (The majority of recommendations are "strong." The strength of each recommendation is noted in the individual working group reports in the supporting information. [See the "Availability of Companion Documents" field.]

Rating Scheme for the Strength of the Recommendations

A "strong" recommendation means that the group is confident that further research would be unlikely to change the recommendation, based on the overall quality of the available evidence, the prospect of obtaining better evidence, and the balance between benefits and harms.

A "weak" recommendation means that there is substantial uncertainty surrounding the balance of benefits and harms, and further research is needed to increase confidence in the results, or that benefits and harms are closely balanced, with decisions based largely on individual preferences and values.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Description of Method of Guideline Validation

After revision, the draft recommendations and rationale were posted on the American Society for Colposcopy and Cervical Pathology (ASCCP) Web site for public comment from October 19, 2011 to November 9, 2011. The public comments were distributed to each Working Group, and revisions were made to address or clarify issues raised. However, each Working Group had the ultimate authority and responsibility for the (revised) draft recommendations presented at the symposium for consideration.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Decreased morbidity and mortality related to cervical cancer due to early detection
- Identification of cervical cancer precursors likely to progress to invasive cancers
- Avoidance of unnecessary treatment of transient human papillomavirus (HPV) infection and its associated benign lesions that are not destined to become cancerous

Potential Harms

- Anxiety associated with a false positive cancer screening test
- Potential stigmatization from the diagnosis of a sexually transmitted infection
- Discomfort from additional diagnostic and treatment procedures
- Bleeding from treatment
- Increased risk of pregnancy complications such as preterm delivery due to treatment

Qualifying Statements

Qualifying Statements

- The recommendations are based on review and assessment of the published peer-reviewed literature available at the time of the symposium. It is anticipated that they will be reviewed on an ongoing basis and revised as new evidence becomes available about the impact of alternative strategies on the balance of benefits and harms associated with cervical cancer screening.
- These recommendations reflect the participants' judgment of the best evidence-based practice for the prevention of cervical cancer morbidity and mortality through currently available screening tests that maximizes protection against cervical cancer while minimizing the potential harms associated with false-positive results and overtreatment.
- These recommendations are for screening only and do not relate to other uses of cytology and human papillomavirus (HPV) testing such as follow-up of patients with untreated disease, post-colposcopic, or immediate post-treatment follow-up/surveillance. Testing at more frequent intervals may be appropriate under such circumstances. For management or abnormal screening results, women should follow American Society for Colposcopy and Cervical Pathology (ASCCP) guidelines.
- While this new screening guideline includes a review of molecular screening tests and strategies, perhaps the largest immediate gain in reducing the burden of cervical cancer incidence and mortality could be attained by increasing access to screening (regardless of the test

used) among women who are currently unscreened or screened infrequently.

- These updated guidelines were developed based on HPV tests that have performance characteristics similar to those of the HPV tests used in the supporting evidence. The guidelines cannot be expected to perform as designed (i.e., to balance benefits and harms) when using HPV tests with different performance characteristics.
- Women who discontinue cervical cancer screening should continue to obtain age-appropriate health care.
- These guidelines do not address special, high-risk populations who may need more intensive or alternative screening. These special populations include women 1) with a history of cervical cancer; 2) who were exposed in utero to diethylstilbestrol (DES); and 3) who are immunocompromised (e.g., infection with the human immunodeficiency virus).

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Implementation Tools

Patient Resources

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1980 (revised 2012 May)

Guideline Developer(s)

American Cancer Society - Disease Specific Society

American Society for Clinical Pathology - Professional Association

American Society for Colposcopy and Cervical Pathology - Medical Specialty Society

Source(s) of Funding

American Cancer Society

American Society for Clinical Pathology

American Society for Colposcopy and Cervical Pathology

Guideline Committee

ACS-ASCCP-ASCP Cervical Cancer Guideline Committee

Composition of Group That Authored the Guideline

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A full list of members of the Working Groups, Data Group, Steering Committee, and Writing Committee is available in the original guideline document.

Financial Disclosures/Conflicts of Interest

In planning this workshop, the Steering Committee critically examined some of the issues involved in defining conflict of interest (COI) and recognized that all interests, whether directly financial or more indirect such as an affiliation with a company, the success of one's clinical practice, or the prominence of a professional specialty, represent potential conflicts. Steering Committee members, Working Group and Data Group co-chairs, and members of the Writing Committee were required not to have any financial ties to companies that market or sell screening tests or devices (e.g., methods to visualize the cervix such as colposcopes). All participating individuals were required to disclose all real or potential COI. Employees or representatives of industry and insurance companies were not invited to participate in the development of these guidelines because of their significant, direct financial interests in the outcome of these guidelines. The complete COI policy can be found in the supporting information (see the "Availability of Companion Documents" field). The complete list of participant disclosures can be found in the original guideline document.

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This is the current release of this guideline.

This guideline updates a previous version: Saslow D, Runowicz CD, Solomon D, Moscicki AB, Smith RA, Eyre HJ, Cohen C. American Cancer Society guideline for the early detection of cervical neoplasia and cancer. *CA Cancer J Clin* 2002 Nov-Dec;52(6):342-62. [88 references]

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the [CA: A Cancer Journal for Clinicians Web site](#)

Print copies: Available from the American Cancer Society, 250 Williams St, Atlanta, GA 30303.

Availability of Companion Documents

The following is available:

- Supporting information. CA Cancer J Clin 2012 May;62(3). 76 p. Electronic copies: Available from the [CA: A Cancer Journal for Clinicians Web site](#) .

Patient Resources

The following are available:

- Testing for cervical cancer. New recommendations from the American Cancer Society, American Society for Colposcopy and Cervical Pathology, and American Society for Clinical Pathology. Patient pages. CA Cancer J Clin 2012 May;62(3). Electronic copies: Available from the [CA: A Cancer Journal for Clinicians Web site](#) .
- Cervical cancer: prevention and early detection. American Cancer Society. 2012. Electronic copies of this and other materials are available from the [American Cancer Society Web site](#) or by calling 1-800-227-2345.

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NGC Status

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